SUMMARY OF THE QUALITY SYSTEMS COMMITTEE TELECONFERENCE OCTOBER 19, 1998

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on October 19, 1998, at 1:00 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of questions concerning NELAC QS is given in Attachment C, and Attachment D is a cross-reference of Section 5.12.3.1 through 5.12.3.4. The agenda for the NELAC Quality Systems Meeting is given in Attachment E. *The purpose of the meeting was to: (a) review action items from the previous meeting, (b) review the recent draft language on calibration and detection; and (c) identify action items for the next meeting.*

ACTION ITEMS

Mr. Slayton forwarded a list of Frequently Asked Questions (FAQ) and responses relating to the QS Chapter (Attachment C) to Ms. Irene.E.Ronning, Chair of the NELAC Membership and Outreach Committee. This was done in response to Ms. Ronning's E-mail of September 21, 1998 requesting NELAC Committee Chairs to pass on such questions received by their committees so they can be posted on the Frequently Asked Questions (FAQ) section of the NELAC World Wide Web site.

Mr. Slayton distributed a revised agenda for the QS Committee meeting in Annapolis, MD from November 8 - 10, 1998. Mr. Slayton will distribute a map showing the US Fish and Wildlife facility which is the site for the meeting on November 8th, and directions to the facility.

Mr. Donivan Porterfield prepared a cross reference of Sections 5.12.3.1 Sample Handling, 5.12.3.2 Laboratory Support Activities, 5.12.3.3 Analytical Records, and 5.12.3.4 Administrative Records with the explicit requirements throughout the QS Chapter, except for appendices. See Attachment D for this cross reference. The QS Committee will explore consolidating the record-keeping requirements specified in the above sections in an appendix and drafting an explanatory paragraph for Section 5.12.3.

Ms. Mary Bruch will evaluate proposed changes to Section D.3.1.b (changing the requirement for monthly positive controls to quarterly) and to Section D.3.6.f (allowing manufacturer documentation of non-inhibition in lieu of performing a check such as an inhibitory residue test).

The draft responses to comments prepared by QS Committee participants will be kept together in a single file for later review by the entire QS Committee.

CALIBRATION AND DETECTION

The committee reviewed and discussed proposed language for Section 5.9.4.3 Instrument Calibrations. The committee is currently focusing on issues regarding calibration and detection. At the next

teleconference, the QS Committee will take up Section 5.9.4.4 Calibration Verification before moving on to analytical detection issues. When these issues are addressed, the QS Committee will attend to comments, in the order in which they were received, regarding Chapter 5.

NEXT MEETING

The next meeting of the QS Committee is scheduled for November 2, 1998 from 1:00 to 3:00 p.m. Eastern Standard Time (EST).

A meeting of the QS Committee is also scheduled for November 8, 9, and 10, 1998 in Annapolis, MD. The meeting is open to the public on Monday, November 9th and on the afternoon of the 10th . The meeting will be held at the US EPA's laboratory on Sunday, November 8th and the remainder of the meeting will be held at the US Fish and Wildlife facility. See Attachment E for the meeting agenda.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
OCTOBER 19, 1998

Item No.	Action Item	Date to be Completed
1.	Next QS Committee teleconference.	November 2nd 1:00 p.m. EST
2.	Mr. Slayton to distribute directions and a map showing sites for the November meeting in Annapolis.	
3.	QS Committee participants to review and draft responses to assigned comments.	Ongoing
4.	Mr. Porterfield to draft introductory paragraph for Section 5.12.3.	
5.	Ms. Bruch to review changing the requirement in Section D.3.1.b for monthly positive controls to quarterly and allowing manufacturer documentation of non-inhibition in lieu of performing a check such as an inhibitory residue test in Section D.3.6.f.	
6.	Mr. Slayton to Fed Ex draft of air monitoring standards.	
7.	Mr. Mike Cross to prepare draft minutes of teleconference.	October 20th
8.	Mr. Cross to compile QS Committee participants draft responses to assigned comments.	Prior to next teleconference

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
OCTOBER 19, 1998

Name	Affiliation	Phone Numbers
Mr. Joe Slayton	USEPA, Region III, OASQA	T: 410-573-2653 F: 410-573-2698 E: slayton.joe@epamail.epa.gov
Ms. Mary K. Bruch	Mary Bruch Micro Reg. Inc.	T: 703- 589-1514 F: 703- 779-0267 E:
Mr. Raymond J. Frederici (Absent)	Recra Labnet - Chicago	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
Mr. Clifford R. Glowacki	Ashland Chemical Company	T: 614-790-3482 F: 614-790-4294 E: cglowacki@ashland.com
Ms. Sylvia S. Labie (Absent)	Florida Department of Environmental Protection	T: 904-488-2796 F: 904-922-4614 E: labie_s@dep.state.fl.us
Mr. David Mendenhall	Utah Department of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
Ms. Sheila Meyers	Texas Natural Resource Conservation Commission	T: 512-239-0425 F: 512-239-6307 E: smeyers@tnrcc.state.tx.us
Mr. Jeff Nielson (Absent)	City of Tallahassee Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Mr. Donivan R. Porterfield	Los Alamos National Laboratory	T: 505-667-4710 F: 505-665-5982 E: dporterfield@lani.gov
Mr. Scott D. Siders	Illinois Environmental Protection Agency	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Ms. Elizabeth Dutrow	US EPA, QAD	T: 202-564-9061 F: 202-565-2441 E: dutrow.elizabeth@epamail.epa.gov
Dr. Fred Siegelman (Absent)	US EPA, QAD	T: 202-564-5173 F: 202-564-2441 E: siegelman.frederic@epamail.epa.gov
Mr. Mike Cross (Contractor Support)	Research Triangle Institute	T: 202-728-2045 F: 202-728-2095 E: myc@rti.org

SOME FREQUENTLY ASKED QUESTIONS CONCERNING NELAC QS (CHAPTER 5):

1. **Question:** If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. **Question:** Do the QS standards require the use of any specific method?

Answer: No

3. **Question**: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. **Question:** Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

This is a cross-reference of section 5.12.3.1 through 5.12.3.4, (July 2, 1998 version) with the explicit requirements throughout the chapter, except appendicees. Those items under "Misc." below don't explicitly map to the categories in 5.12.3.1 through 5.12.3.4.

Misc.	
5.5.2	The Quality Manual shall list on the title page: a document title; the laboratory's full name and address; the name, address (if different from above), and telephone number of individual(s) responsible for the laboratory; the name of the quality assurance officer (however named); the identification of all major organizational units which are to be covered by this quality manual and the effective date of the version;
5.5.2(a)	The quality manual and related quality documentation shall also contain … a quality policy statement, including objectives and commitments, by top management;
5.5.2(b)	The quality manual and related quality documentation shall also contain … the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;
5.5.2(c)	The quality manual and related quality documentation shall also contain … the relationship between management, technical operations, support services and the quality system;
5.5.2(f)	The quality manual and related quality documentation shall also contain … identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual must have the signed concurrence, (with appropriate titles) of all responsible parties including the QA officer, technical director, and the agent who is in charge of all laboratory activities such as the laboratory director or laboratory manager;
5.5.2(i)	The quality manual and related quality documentation shall also contain … mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;
5.5.2(v)	The quality manual and related quality documentation shall also contain … a Table of Contents, and applicable lists of references and glossaries, and appendices.
5.6.2(d)	Documenting all analytical and operational activities of the laboratory;
5.10.2.1(c)	In all cases, the appropriate forms such as the Certification Statement (Appendix C) or standard performance checklists (see Appendix E) must be completed and retained by the laboratory to be made available upon request. All associated supporting data necessary to reproduce the analytical results summarized in the checklists must be retained by the laboratory.
5.12.1	All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification shall be documented.

5.12.2(d)	The laboratory shall establish a record management system for control of laboratory notebooks; instrument logbooks; standards logbooks; and records for data reduction, validation storage and reporting;
5.15(c)	The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.

This is a cross-reference of section 5.12.3.1, "Sample Handling", (July 2, 1998 version) with the explicit requirements throughout the chapter, except appendicees.

Sample preservation including appropriateness of sample container and compliance with holding time requirement;	

Sample identification, receipt, acceptance or rejection and log-in;	
5.11.2	The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted. Data from any samples which do not meet the following criteria must be flagged in an unambiguous manner clearly defining the nature and substance of the variation. This sample acceptance policy shall be made available to sample collection personnel and shall include, but is not limited to, the following areas of concern:
5.11.2(a)	Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample;
5.11.2(f)	Procedures to be used when samples which show signs of damage or contamination.
5.11.3(a)	Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified in 5.11.2 above shall be checked.
5.11.3(b)	The results of all checks shall be recorded.

Sample storage and tracking including shipping receipts, transmittal forms, and internal routing and assignment records;	
5.5.2(k)	The quality manual and related quality documentation shall also contain … procedures for handling submitted samples;
5.11.1(a)	The laboratory shall have a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time. This system shall include identification for all samples, subsamples and subsequent extracts and/or digestates. The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample.
5.11.1(d)	The laboratory ID code shall be entered into the laboratory records (see 5.11.3.d) and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration.
5.11.3(d)	The laboratory shall utilize a permanent chronological record such as a log book or electronic database to document receipt of all sample containers.
5.11.3(d)(2)	During the log in process, the following information must be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample. Note: the placement of the laboratory ID number on the sample container is not considered a permanent record.
5.11.3(f)	A complete chain of custody record (Section 5.12.4), if utilized, shall be maintained.
5.11.4	The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary.
5.12.4.2	In addition to the information specified in 5.11.1.a and 5.11.1.b, tracking records shall include, by direct entry or linkage to other records: a) Time of day and calendar date of each transfer or handling procedure; b) Signatures of all personnel who physically handle the sample(s); c) All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting; and d) Common carrier documents.
5.14	a) The laboratory shall advise the client in writing of its intention to sub-contract any portion of the testing to another party. b) Where a laboratory sub-contracts any part of the testing covered under NELAP, this work shall be placed with a laboratory accredited under NELAP for the tests to be performed. c) The laboratory shall retain records demonstrating that the above requirements have been met.

Sample preparation including cleanup and separation protocols, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

Sample analysis;	

Standard and reagent origin, receipt, preparation, and use;	
5.9.2(b)	Calibration certificates shall when available indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory shall maintain records of all such certifications.
5.9.2(c)	Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis.
5.10.5	Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.
5.10.5(a)	The laboratory shall retain records for all standards including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless it is verified by the laboratory.
5.10.5(c)	Detailed records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

Equipment receipt, use, specification, operating conditions and preventative maintenance;	
5.5.2(l)	The quality manual and related quality documentation shall also contain … reference to the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;
5.5.2(m)	The quality manual and related quality documentation shall also contain … reference to procedures for calibration, verification and maintenance of equipment;
5.7.1(d)	In instances where monitoring or control of any of the above mentioned items are specified in a test method or by regulation, the laboratory shall meet and document adherence to the laboratory facility requirements.
5.8(b)	All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented.
5.8(e)	Records shall be maintained of each major item of equipment and all reference materials significant to the tests performed. These records shall include documentation on all routine and non-routine maintenance activities and reference material verifications. The records shall include: 1) the name of the item of equipment; 2) the manufacturer's name, type identification, and serial number or other unique identification; 3) date received and date placed in service (if available); 4) current location, where appropriate; 5) if available, condition when received (e.g. new, used, reconditioned); 6) copy of the manufacturer's instructions, where available; 7) dates and results of calibrations and/or verifications and date of the next calibration and/or verification; 8) details of maintenance carried out to date and planned for the future; and 9) history of any damage, malfunction, modification or repair.
5.9.4.2.1(a)	maintained in proper working order. The records of all activities including service calls shall be kept.
5.9.4.2.2	The sterilization temperature and pressure of each run must be documented by the use of appropriate chemical or biological sterilization indicators. Autoclave tape may be used to indicate by color change that a load has been processed, but not to demonstrate completion of an acceptable sterilization cycle. Demonstration of sterilization may be provided by a continuous temperature recording or with the use of spore strips.
5.10.1(a)	The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests.
5.10.1(b)	All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

Calibration criteria, frequency and acceptance criteria;	
5.5.2(g)	The quality manual and related quality documentation shall also contain … the laboratory's procedures for achieving traceability of measurements;
5.9.4.1(b)	Sufficient information shall be recorded to permit reconstruction of the calibration.
5.9.4.1(c)	Criteria for the acceptance of a calibration procedure, such as calibration curves and concentration (titer) determinations of titrants, shall be established. If applicable, the method specified criteria shall be met.
5.9.4.2.1(b)(2)	The laboratory shall prepare a deviation curve and correct all measurements for the deviation. All measurements shall be recorded and maintained.

Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;	
5.12	The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. The system shall produce unequivocal, accurate records which document all laboratory activities. The laboratory shall retain on record all original observations, calculations and derived data, calibration records and a copy of the test report for an appropriate period.

Method performance criteria including expected quality control requirements;	
5.5.2(j)	The quality manual and related quality documentation shall also contain … reference to the calibration and/or verification test procedures used;

Quality control protocols and assessment;	

Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;	
5.10.6(b)	computer software is documented and adequate for use;
5.10.6(c)	procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;
5.10.6(e)	it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.
5.12.2(c)	Records that are stored or generated by computers or personal computers (PCS) shall have hard copy or write-protected backup copies.

All automated sample handling systems; and

Disposal of hazardous samples including the date of sample or subsample disposal and name of the responsible person.	
5.11.5	The laboratory shall have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.
5.12.4.5(b)	All conditions of disposal and all correspondence between all parties concerning the final disposition of the physical sample shall be recorded and retained.
5.12.4.5(c)	Records shall indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to client), and the name of the individual who performed the task.

This is a cross-reference of section 5.12.3.2, "Laboratory Support Activities ", (July 2, 1998 version) with the explicit requirements throughout the chapter, except appendices.

All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);	

A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;	

Copies of final reports;	
5.5.2(u)	The quality manual and related quality documentation shall also contain … reference to procedures for reporting analytical results; and

Archived standard operating procedures;	
5.5.1(a)	The elements of this quality system shall be documented in the organization's quality manual.
5.5.1(c)	The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.
5.5.1(d)	The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned.
5.5.2(d)	The quality manual and related quality documentation shall also contain … procedures to ensure that all records required under this Chapter are retained, as well as procedures for control and maintenance of documentation through a document control system which ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force;
5.5.2(h)	The quality manual and related quality documentation shall also contain … a list of all test methods under which the laboratory performs its accredited testing;

5.10.1.1	Laboratories shall maintain standard operating procedures that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods. a) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents. b) The test methods may be copies of published methods as long as any changes in the methods are documented and included in the methods manual (see 5.10.1.2). c) Copies of all SOPs shall be accessible to all personnel. d) The SOPs shall be organized . e) Each SOP shall clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority.
5.10.1.2(a)	The laboratory shall have and maintain an in-house methods manual(s) for each accredited analyte or test method.
5.10.2(a)(2)	Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see 5.10.2.1), and be available to the client and other recipients of the relevant reports.
5.10.3	Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.

Correspondence relating to laboratory activities for a specific project;	
5.4.2(i)	The quality assurance officer (and/or his/her designees) shall … have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights (this may not apply to in-house laboratories);
5.5.2(q)	The quality manual and related quality documentation shall also contain … procedures for dealing with complaints;
5.5.2(r)	The quality manual and related quality documentation shall also contain … procedures for protecting confidentiality (including national security concerns), and proprietary rights;
5.5.3.1	Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

5.11.3(c)	Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, the laboratory should consult the client for further instruction before proceeding. The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory. If the sample does not meet the sample receipt acceptance criteria listed in 5.11.3.a, 5.11.3.b or 5.11.3.c, the laboratory shall either: 1) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or 2) Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.
5.11.3(e)	All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter shall be retained.
5.13(e)	The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.
5.13(f)	The laboratory shall ensure that, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Standard are met and that confidentiality is preserved.
5.16	The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Standard or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with Section 5.5.3.1. Records of the complaint and subsequent actions shall be maintained.

All corrective action reports, audits and audit responses;	
5.5.2(o)	The quality manual and related quality documentation shall also contain … procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;
5.5.2(p)	The quality manual and related quality documentation shall also contain … the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;
5.5.2(s)	The quality manual and related quality documentation shall also contain … procedures for audits and data review;

5.5.3.3	All audit and review findings and any corrective actions that arise from them shall be documented.

Proficiency test results and raw data; and	
5.5.2(n)	The quality manual and related quality documentation shall also contain … reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;
5.6.2(b)	Ensuring that all technical laboratory staff have demonstrated initial and ongoing proficiency in the activities for which they are responsible. Such demonstration shall be documented;

Data review and cross checking.	
5.6.2(g)	Documenting the quality of all data reported by the laboratory.
5.10.4(a)	The laboratory shall establish Standard Operating Procedures to ensure that the reported data is free from transcription and calculation errors.
5.10.4(b)	The laboratory shall establish a Standard Operating Procedures to ensure that all quality control measures are reviewed, and evaluated before data are reported.

This is a cross-reference of section 5.12.3.3, "Analytical Records", (July 2, 1998 version) with the explicit requirements throughout the chapter, except appendicees.

Laboratory sample ID code;	

Date of analysis;	

Instrumentation identification and instrument operating conditions/parameters (or reference to such data);	

Analysis type;	

All manual calculations ; and

Analyst's or operator's initials/signature.	

This is a cross-reference of section 5.12.3.4, "Administrative Records", (July 2, 1998 version) with the explicit requirements throughout the chapter, except appendicees.

Personnel qualifications, experience and training records;	
5.4.2(d)	specify and document the responsibility, authority, and interrelationship of all personnel who manage, perform or verify work affecting the quality of calibrations and tests; Such documentation shall include: 1) a clear description of the lines of responsibility in the laboratory and shall be proportioned such that adequate supervision is ensured and 2) job descriptions for all positions.
5.4.2(f)	The technical director(s) shall certify that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited. Such certification shall be documented.
5.4.2(g)(4)	The quality assurance officer (and/or his/her designees) shall … have documented training and/or experience in QA/QC procedures and be knowledgeable in the quality system as defined under NELAC;

5.5.2(e)	The quality manual and related quality documentation shall also contain … job descriptions of key staff and reference to the job descriptions of other staff;
5.5.2(t)	The quality manual and related quality documentation shall also contain … processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training;
5.6.2(c)(1)	Evidence must be on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities.
5.6.2.(c)(2)	Training courses or workshops on specific equipment, analytical techniques or laboratory procedures shall all be documented.
5.6.2.(c)(3)	Analyst training shall be considered up to date if an employee file contains a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:

Initial and continuing demonstration of proficiency for each analyst; and	
5.6.3	Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory [see 5.6.2.c)], including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.10.2.1 for chemical testing.

A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.	

Attachment E

AGENDA

NELAC QUALITY SYSTEMS MEETING

Date: November 8 (Sunday- For Committee Members Only- Closed Session)

Location: USEPA, 839 Bestgate Road, Annapolis Maryland
Conference Room Phone Number (if you have problems, QS Members, are to call): 410-573-2692 to get access to the building on Sunday.

10 AM - 3 PM	Instrument Calibration and Detection
3-4 Lunch/Brunch	(Mike's Crab House or somewhere outside as the weather permits)
4-5 PM	Business/Administrative Items

Date: November 9 (Monday- **Session Open to all: Please contact Joe Slayton in advance, 410-573-2653, if you are not a QS member)**.

Teleconference Access: 202-260-8330 (Access Code 2461#, 9AM- 5 PM Eastern)

Location: US Fish and Wildlife, 177 Admiral Cochran Drive, Annapolis, Md 21401):410-573-4500 or Drew Windsor at 410-573-4570.

9 AM- 10	Calibration & Detection QS Approach (Overview and Specifics)
10-10:30	EMMC Input Calibration & Detection: (Suggestions/Comments/Alternative Proposal)
10:30-12	Open/Panel Discussion on Calibration & Detection
12-1	Lunch Location TBD (Sam's Cafe or Annapolis Landing Marina ?)
1- 5	Discussion from QS Session Leaders on Comments Received to Date (Those Not Completed and Posted on the Web Site by Nov. 9th)

Date: November 10 (Tuesday- **10- Noon Closed; Noon- 2 PM Session Open to all: Please contact Joe Slayton in advance, 410-573-2653, if you are not a QS member)**

Teleconference Access: 202-260-8330 (Access Code 2461#, Noon-2 PM)

Location: US Fish and Wildlife, Same as above

10-Noon	QS for Air Analyses (**Closed Session)**
12-1	Lunch Location TBD (Sam's Cafe or Annapolis Landing Marina ?)
1- 2	Open Discussion on QS for Air Analyses.